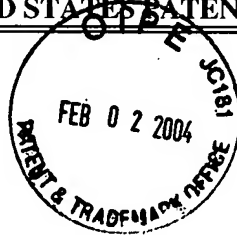


**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s):	LOVAS et al.	Group Art Unit:	Unassigned
Serial No.:	10/695,382	Examiner: ::	Unassigned
Filed:	28 October 2003	Docket No.:	180.0005 0102
Title:	NOVEL GnRH ANALOGUES WITH ANTITUMOUR EFFECTS AND PHARMACEUTICAL COMPOSITIONS THEREOF		



Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

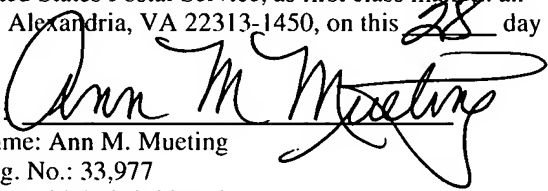
- ☒ **Small entity status is entitled to be asserted in the above-identified application.**
- ☒ An itemized return postcard.
- ☐ A Petition for Extension of Time for \_\_ month(s) and a check in the amount of \$\_\_ for the required fee.
- ☒ An Information Disclosure Statement (2 pgs); copies of 0 applications; 1449 forms (7 pgs); and copy of 1 document cited on the 1449 forms.
- ☐ A check in the amount of \$\_\_, representing \_\_.
- ☐ A certified copy of a \_\_ application, Serial No. \_\_, filed \_\_\_\_, the right of priority of which is claimed under 35 U.S.C. §119.
- ☐ Other: \_\_.
- ☐ Amendment ☐ No Additional fee is required. ☐ The fee has been calculated as shown:

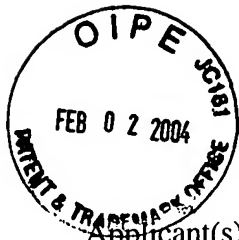
Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$9 =	
Independent Claims				x \$43 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$145 Here →					
Total Additional Claim Fees Required					\$0

**Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.**

**CERTIFICATE UNDER 37 C.F.R. §1.8:** The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 28 day of January, 2004.

MUETING, RAASCH & GEBHARDT, P.A.  
Customer Number: 26813

By   
Name: Ann M. Mueeting  
Reg. No.: 33,977  
Direct Dial: 612-305-1217  
Facsimile: 612-305-1228



PATENT  
Docket No.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Lovas et al.	)	Group Art Unit:	Unassigned
		)		
Serial No.:	10/695,382	)	Examiner:	Unassigned
Confirmation No.:	Unknown	)		
		)		
Filed:	28 October 2003	)		

For: NOVEL GnRH ANALOGUES WITH ANTITUMOUR EFFECTS AND  
PHARMACEUTICAL COMPOSITIONS THEREOF

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. § 609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

This application is a divisional of U.S. Patent 6,664,369, issued 16 December 2003 (copy enclosed). In accordance with 37 C.F.R. § 1.98(d), copies of documents previously cited by or submitted to the U.S. Patent and Trademark Office in connection with Applicants' prior application(s) listed above, are not included herewith.

**Information Disclosure Statement**

Page 2 of 2

Applicant(s): Lovas et al.  
Serial No.: 10/695,382  
Filed: 28 October 2003  
For: NOVEL GnRH ANALOGUES WITH ANTITUMOUR EFFECTS AND PHARMACEUTICAL COMPOSITIONS THEREOF

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It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

Respectfully submitted for

**LOVAS et al.,**

By  
Muetting, Raasch & Gebhardt, P.A.  
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**CERTIFICATE UNDER 37 C.F.R. 1.8:**

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 28<sup>th</sup> day of January, 2004

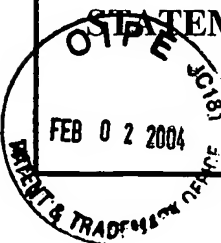
Signature: Kelly J. McNulty  
Printed Name: Kelly J. McNulty

January 28, 2004  
Date

AMM/kjm

By:

Ann M. Muetting  
Ann M. Muetting  
Reg. No. 33,977  
Direct Dial (612)305-1217

<b>INFORMATION DISCLOSURE STATEMENT</b> 	Atty. Docket No.: 180.0005 0102	Serial No.: 10/695,382
	Applicant(s): Lovas et al.	Confirmation No.: Unknown
	Application Filing Date: 10/28/2003	Group: 1653
	Information Disclosure Statement mailed: <u>28</u> January 2004	


## U.S. PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		3,871,964	03/18/1975	Hüper et al.			
		4,116,742	09/26/1978	Firth			
		4,424,079	01/03/1984	Barabas			
		4,833,166	05/23/1989	Grosvenor et al.			
		4,975,420	12/04/1990	Silversides et al.			
		5,593,965	01/14/1997	Lovas et al.			
	X	6,664,369	12/16/2003	Lovas et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
		0 368 449 A2, A3	05/16/90	EPO				
		34519	03/28/85	Hungary (with Engl. language abstract)				X
		212 661 A	11/28/96	Hungary			X	
		212 662 A	11/28/96	Hungary			X	
		9-508142	08/19/97	Japan (with Engl. language abstract)				X
		WO 96/04927	02/22/96	PCT				

<b>EXAMINER</b>	<b>Date Considered</b>
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<b>INFORMATION DISCLOSURE STATEMENT</b> 	Atty. Docket No.: 180.0005 0102	Serial No.: 10/695,382
	Applicant(s): Lovas et al.	Confirmation No.: Unknown
	Application Filing Date: 10/28/2003	Group: 1653
	Information Disclosure Statement mailed: 28 January 2004	

### OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Copy Enclosed	Document Description
		Azori et al., "Synthesis, elimination, and whole-body distribution of $^{14}\text{C}$ -labelled drug carrier," <u>Die Makromolekulare Chemie</u> , 187(2):297-302 (1986).
		Bokser et al., "Inhibition of pituitary-gonadal axis in mice by long-term administration of D-Trp-6-LHRH microcapsules," <u>Journal of Reproduction and Fertility</u> , 85(2):569-574 (1989).
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		Butler, "Synthesis and Properties of Novel Polyanions of Potential Antitumor Activity," <u>Journal of Macromolecular Science - Chemistry</u> , A13(3):351-368 (1979).
		Cailleau et al., "Breast Tumor Cell Lines From Pleural Effusions," <u>Journal of the National Cancer Institute</u> , 53(3):661-674 (1974).
		Creighton University, "Creighton Scientists and Hungarian Partners Develop Promising Therapy for Breast and Prostate Cancers," Creighton University Public Relations Department Press Release, 2 pages (March 31, 1999).
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		Eidne et al., "Gonadotropin-Releasing Hormone Binding Sites in Human Breast Carcinoma," <u>Science</u> , 229(4717):989-991 (1985).
		Eidne et al., "Gonadotropin-Releasing Hormone (GnRH)-Binding Sites in Human Breast Cancer Cell Lines and Inhibitory Effects of GnRH Antagonists," <u>Journal of Clinical Endocrinology and Metabolism</u> , 64(3):425-432 (1987).
		Gaál et al., "Immunomodulatory Effect of Synthetic Branched Polypeptides. II.," <u>Journal of Biological Response Modifiers</u> , 5(2):148-159 (1986).
		Glass, John, D., "Enzymatic Manipulation of Protecting Groups in Peptide Synthesis," <u>The Peptides</u> , Udenfriend et al., eds., Academic Press, Inc., San Diego, Title page, publication page, table of contents, pp. 178 and 253 (1987).

EXAMINER	Date Considered
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**INFORMATION  
DISCLOSURE  
STATEMENT**

Atty. Docket No.: 180.0005 0102

Serial No.: 10/695,382

Applicant(s): Lovas et al.

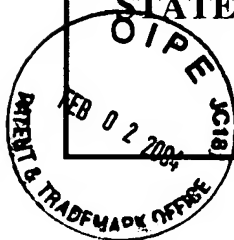
Confirmation No.: Unknown

Application Filing Date: 10/28/2003

Group: 1653


Information Disclosure Statement  
mailed:

28 January 2004



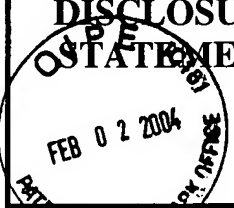
Examiner Initial	Copy Enclosed	Document Description
		Gros, "Biological Activity," <u>Encyclopedia of Polymer Science and Engineering</u> , Vol. 2, John Wiley & Sons, Inc., New York, Title page, publication page, and pages 243-267 (1985).
		Harris et al., "Gonadotropin-releasing Hormone Gene Expression in MDA-MB-231 and ZR-75-1 Breast Carcinoma Cell Lines," <u>Cancer Research</u> , 51(10):2577-2581 (1991).
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		Mező et al., "GnRH analogs and their conjugates with enhanced antitumor activity," Proceedings of the Twenty Third European Peptide Symposium, September 4-10, 1994, Braga, Portugal, <u>Peptides 1994</u> , pages 763-764 (1995).

<b>EXAMINER</b>	<b>Date Considered</b>
<p>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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	Applicant(s): Lovas et al.	Confirmation No.: Unknown
	Application Filing Date: 10/28/2003	Group: 1653
	Information Disclosure Statement mailed: <u>28</u> January 2004	

Examiner Initial	Copy Enclosed	Document Description
		Mezo et al., "GnRH analogs and their conjugates with enhanced antitumor activity," Proceedings of the European Peptide Symposium, September 23, 1994, <u>Peptides</u> , pages 763-764, <u>Chemical Abstracts</u> , 125(25): abstract no. 316399 (1996).
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		Ottenbrite, "Antitumor Activity of Polycarboxylic Acid Polymers," <u>Journal of Macromolecular Science- Chemistry</u> , A22(5-7):819-832 (1985).
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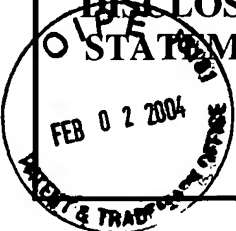
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	<b>Applicant(s):</b> Lovas et al.	<b>Confirmation No.:</b> Unknown
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	Information Disclosure Statement mailed: <u>28</u> January 2004	

Examiner Initial	Copy Enclosed	Document Description
		Reddy et al., "Preparation of potentially electroactive thallium polymers derived from the acidic copolymers of maleic anhydride," <u>Polymer</u> , <u>25</u> (1):115-120 (1984).
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		Scott et al., "Factors Influencing the Response of MCF-7 Cells to an Agonist of Luteinising Hormone-releasing Hormone," <u>European Journal of Cancer</u> , <u>27</u> (11):1458-1461 (1991).
		Segal-Abramson et al., "Guanine nucleotide modulation of high affinity gonadotropin-releasing hormone receptors in rat mammary tumors," <u>Molecular and Cellular Endocrinology</u> , <u>85</u> (1-2):109-116 (1992).
		Segal-Abramson et al., "Direct effects of luteinizing hormone-releasing hormone agonists and antagonists on MCF-7 mammary cancer cells," <u>Proceedings of the National Academy of Sciences USA</u> , <u>89</u> (6):2336-2339 (1992).
		Sharoni et al., "Inhibition of growth of human mammary tumor cells by potent antagonists of luteinizing hormone-releasing hormone," <u>Proceedings of the National Academy of Sciences USA</u> , <u>86</u> (5):1648-1651 (1989).
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	<b>Applicant(s):</b> Lovas et al.	<b>Confirmation No.:</b> Unknown
	<b>Application Filing Date:</b> 10/28/2003	<b>Group:</b> 1653
	Information Disclosure Statement mailed: <u>28</u> January 2004	

Examiner Initial	Copy Enclosed	Document Description
		"Table 1. Breast Cancer incidence in women in Australia, 1990," National Breast Cancer Centre, National Health and Medical Research Council [online]. Sydney, Australia, October 11, 1995 [retrieved March 18, 1996]. Retrieved from the Internet: <URL: <a href="http://www.nbcc.org.au/pages/table1.htm">http://www.nbcc.org.au/pages/table1.htm</a> >, 1 page.
		"Table 2. Breast Cancer Incidence Worldwide," National Breast Cancer Centre, National Health and Medical Research Council [online]. Sydney, Australia, October 10, 1995 [retrieved March 23, 1996]. Retrieved from the Internet: <URL: <a href="http://www.nbcc.org.au/pages/table2.htm">http://www.nbcc.org.au/pages/table2.htm</a> >, 1 page.
		"Table 3. Estimates of breast cancer incidence and mortality in women in some countries of the European Union and in Australia," National Breast Cancer Centre, National Health and Medical Research Council [online]. Sydney, Australia, October 11, 1995 [retrieved March 18, 1996]. Retrieved from the Internet: <URL: <a href="http://www.nbcc.org.au/pages/table3.htm">http://www.nbcc.org.au/pages/table3.htm</a> >, 1 page.
		Tabor et al., eds., "IUPAC-IUB Commission on Biochemical Nomenclature Symbols for Amino-Acid Derivatives and Peptides, Recommendations (1971)," <u>Journal of Biological Chemistry</u> , 247(4):977-983 (1972).
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		Vincze et al., "Influence of luteinizing hormone-releasing hormone agonists on human mammary carcinoma cell lines and their xenografts," <u>Journal of Steroid Biochemistry and Molecular Biology</u> , 38(2):119-126 (1991).
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	Information Disclosure Statement mailed: <u>28</u> January 2004	

Examiner Initial	Copy Enclosed	Document Description
		Yano et al., "Inhibition of growth of MCF-7 MII human breast carcinoma in nude mice by treatment with agonists or antagonists of LH-RH," <u>Breast Cancer Research and Treatment</u> , <u>21</u> (1):35-45 (1992).

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